K081437
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GE Medical Systems
Information Technologies

JUL 15 2008

## 5.0 510(k) Summary

## 5.1 Applicant and Contact Information

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| **5.1.1 Submitter/Manufacturing Information** | | GE Medical Systems Information Technologies<br>9900 Innovation Drive<br>Wauwatosa, WI 53226 |
| **5.1.2 Establishment Registration**<br>**[per 21 CFR 807.87(b)]** | | Active; Awaiting Assignment of Registration Number |
| **5.1.3 Contact Person** | Primary: | Margaret Mucha<br>Regulatory Affairs Leader<br>GE Medical Systems Information Technologies<br>RP-2122<br>9900 Innovation Drive<br>Wauwatosa, WI 53226<br>Telephone: 414-721-4535<br>Fax: 414-721-3863<br>E-mail: margaret.mucha@ge.com |
| | Secondary: | Matthias Buerger<br>Director QA/RA Diagnostic Cardiology<br>GE Medical Systems Information Technologies<br>RP-2122<br>9900 Innovation Drive<br>Wauwatosa, WI 53226<br>Telephone: 414-721-2317<br>Fax: 414-721-3899<br>E-mail: Matthias.Buerger@ge.com<br><br>Tracey Fox<br>Regulatory Programs Manager<br>GE Healthcare<br>3000 N. Grandview Blvd W-418<br>Waukesha, WI 53188<br>Telephone: (262) 513-4061<br>E-mail: Tracey.Fox@ge.com |

## 5.2 Basic Device Identification

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| **5.2.1** | Device Name | MAC 1600 ECG Analysis System | | |
| **5.2.2** | Device Proprietary Name **[per 21 CFR 807.87(a)]** | MAC 1600 ECG Analysis System | | |
| **5.2.3** | Common/Usual Name **[per 21 CFR 807.87(a)]** | Electrocardiograph | | |
| **5.2.4** | Classification Names/Numbers and Code **[per 21 CFR807.87(a)]** | **21 CFR** | **Classification Name** | **Code** |
| | | 870.2340 | Electrocardiograph | DPS |
| | | 870.1425 | Programmable Diagnostic Computer | DQK |
| | | 870.2920 | Transmitters and Receivers, Electrocardiograph, Telephone | DXH |
| **5.2.5** | Regulatory Class **[per 21 CFR 807.87(c)]** | II | | |

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| **5.2.6** Prescription Status | Prescription Device |
| **5.2.7** Device/Classification Panel **[per 21 CFR 807.87(c)]** | Cardiovascular |
| **5.2.8 Predicate Device** | CardioSmart ST V1.3 (K973403) and CASE/Cardiosoft (K031561) |
| **5.2.9 Sterilization Site** | Not Applicable, device is sold in a non-sterile condition. |
| **5.2.10 Sec 514 Performance Standards** **[per 21 CFR 807.87(d)]** | No applicable performance standards have been established under Section 514 of the Federal Food, Drug and Cosmetic Act for the device subject of this submission. The MAC 1600 ECG Analysis System complies with the voluntary standards as detailed in Section 9 of this submission. |
| **5.2.11 Technology** | The technological characteristics of the MAC 1600 have been updated to reflect use of current technology and to incorporate user requested features. Data in this submission demonstrate that these technological characteristics do not raise new questions of safety or effectiveness |
| **5.2.12 Device Description** | The MAC 1600 ECG acquisition, analysis and recording system can print and display multiple leads of ECG data. MAC1600 is also capable of acquiring 2 additional ECG leads beyond what is needed for classical 12 lead ECG acquisition. The MAC 1600 will provide, in resting ECG mode, ECG quality information using the hookup advisor. The hookup advisor advises users of poor lead quality based on noise measurement. It can be upgraded to provide options such as ECG measurement and interpretation with 12SL as well as a stress testing option for exercise stress testing. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is also optional. Multiple QT correction formulas including Bazett, Framingham and Fridericia will be available as a user selectable option. Clinical Trials Data Guard and audit trail options are also available to support electronic record requirements.<br><br>The MAC 1600 delivers multiple leads of ECG on full-size reports and includes an alphanumeric keyboard for patient demographics and other data entry, an integrated 7" color display, and an integrated thermal writer. The thermal writer will print real time continuous waveform, alphanumeric data and non real time reports. The device will have optional internal memory and removable storage to store resting ECG records. An optional barcode reader to enter patient information is available. The MAC 1600 can be used as a portable unit. |
| **5.2.13 Intended Use** | The MAC1600 is a portable ECG acquisition, analysis and recording system. The MAC1600 is intended to acquire, analyze, display and record information from adult and pediatric populations. Pediatric population is defined as patients between the ages of 0 and 15 years. The MAC1600 is intended to be used by trained operators in a hospital or medical professional's facility environment to record ECG signals from surface electrodes. The basic system shall provide 2 modes of operation: (1) Resting ECG mode and (2) Arrhythmia mode. The basic systems shall print 6 or 12-leads of ECG. The device shall be upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis. The basic system shall be upgradeable with a third mode of operation: (3) Exercise mode for exercise stress testing. Transmission and reception of ECG data to and from a central ECG cardiovascular information system shall be optional. The arrhythmia detection |

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| | portion of the MAC 1600 is provided to the customer for the convenience of automatic documentation.<br><br>The MAC1600 is used under the direct supervision of a licensed healthcare practitioner.<br><br>The MAC 1600 is not designed to provide alarms for arrhythmia detection.<br>The device is not suitable for intra cardiac application.<br>It is not intended for use:<br>• As a vital signs physiological monitor; or<br>• For use during patient transport. |
| **5.2.14 Conclusion** | The MAC 1600 ECG Analysis System is similar to existing CardioSmart ST and CASE/Cardiosoft devices incorporating features that have been previously cleared under different 510(k)'s. This premarket notification submission demonstrates that the MAC 1600 ECG Analysis System is substantially equivalent to the previously cleared devices and differences in technological characteristics do not raise new questions of safety or effectiveness. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 15 2008

GE Medical Systems Information Technologies
c/o Ms. Margaret Mucha
Regulatory Affairs Leader
9900 Innovation Drive, RP-2122
Wauwatosa, WI 53226

Re: K081437
Trade Name: MAC 1600 ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DQK, and DXH
Dated: May 21, 2008
Received: May 22, 2008

Dear Ms. Mucha:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

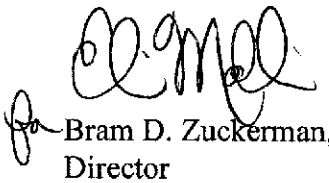
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081437

GE Medical Systems
Information Technologies

510(k) Number (if known):

Device Name: MAC 1600 ECG Analysis System

Indications for Use:

The MAC1600 is a portable ECG acquisition, analysis and recording system. The MAC1600 is intended to acquire, analyze, display and record information from adult and pediatric populations. Pediatric population is defined as patients between the ages of 0 and 15 years. The MAC1600 is intended to be used by trained operators in a hospital or medical professional's facility environment to record ECG signals from surface electrodes. The basic system shall provide 2 modes of operation: (1) Resting ECG mode and (2) Arrhythmia mode. The basic systems shall print 6 or 12-leads of ECG. The device shall be upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis. The basic system shall be upgradeable with a third mode of operation: (3) Exercise mode for exercise stress testing. Transmission and reception of ECG data to and from a central ECG cardiovascular information system shall be optional. The arrhythmia detection portion of the MAC 1600 is provided to the customer for the convenience of automatic documentation.

The MAC1600 is used under the direct supervision of a licensed healthcare practitioner.

**Contraindications:**

The MAC 1600 is not designed to provide alarms for arrhythmia detection.
The device is not suitable for intra cardiac application.
It is not intended for use:

- As a vital signs physiological monitor; or
- For use during patient transport.

Prescription Use ____√_____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K081437